REMARKS

Applicants have amended the claims to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have amended claims 2, 3 and 9 in an effort to expedite the prosecution to remove terms objected to by the Examiner in the Official Action. Applicants note that Applicants election without traverse of Group I, claims 1-29, in the reply filed on 6 March 2007 is acknowledged. Accordingly, Applicants have canceled claims 30-36 from the present application. Applicants retain their right to file a divisional application to the non-elected invention at a later time.

Applicants submit that the claims now present in the application, claims 1-29, are fully supported by the specification as originally filed and are in full compliance with 35 USC 112.

The rejection of claims 1-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

At the outset, Applicants wish to note MPEP §2173.02 Clarity and Precision. As noted therein, the examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not whether more suitable language or modes of expression are available.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

In reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. 112, second paragraph, by providing clear warning to others as to what constitutes infringement of the patent. See, e.g., Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). See also In re Larsen, No. 01-1092 (Fed. Cir. May 9, 2001) (unpublished) (The preamble of the *Larsen* claim recited only a hanger and a loop but the body of the claim positively recited a linear member. The court observed that the totality of all the limitations of the claim and their interaction with each other must be considered to ascertain the inventor's contribution to the art. Upon review of the claim in its entirety, the court concluded that the claim at issue apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function.

Applicants most respectfully submit that it would be clear to one skilled in the art that claim 1 relates to a seal for a valve for use in a pharmaceutical dispensing device. The word seal is the second word in the claim and provides the antecedent basis for "which" in line 2 of the claim. Accordingly, it is most respectfully requested that there is antecedent basis for "which seal" in lines 1 and 2 in all of the claims. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

The recitation of "derivatives thereof" does not believe to render the claims indefinite but has been canceled from claims 2 and 3 as unnecessary in view of the scope of the claims and the level of ordinary skill in the art and to expedite the prosecution and reduce the issues. Moreover, it is noted that the use of this term has not been rejected in claims 1 and 8, for example, and therefore, it has not been canceled from claim 5. It is most respectfully submitted that the use of this term, in the context of the claims and as would be understood by one of ordinary skill in the art does

not render the claims indefinite. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

Claim 9 has been amended to refer to the substituted dithiocarbonate to provide antecedent basis in the claim for isopropyl. See also page 8 of Applicants' specification. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

Applicants most respectfully submit that it is clear claim 1 is directed to seal for a valve for a pharmaceutical dispensing device and includes the following limitations:

As a cross-linking agent:	*sulphur or a sulphur-donating compound, the cross-linking agent being free of peroxide curing agents.*
As an accelerator:	*a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof.*

The Official Action appears to suggest that a polysulphide compound derived from a substituted dithiocarbonic acid is not a "product" feature but instead is a "process" feature which imparts no limitation on claim 1. While a polysulphide compound derived from a substituted dithiocarbonic acid does perhaps indicate some history about the compound, it also imposes a product limitation as would be understood by one of ordinary skill in the art to which the invention pertains. The polysulphide compound is derived from a substituted dithiocarbonic acid and thus this limits the product in the sense that the claim does not encompass polysulphide compounds derived from an unrelated acid. Accordingly, it is most respectfully requested that this rejection be withdrawn.

Applicants most respectfully submit that all of the claims now present in the application are in full compliance with 35 USC 112 and clearly patentable over the references of record.

The rejection of claims 1-5, 8-9, 12-22 and 28 under 35 U.S.C. 102(b) as being anticipated by Kaszas et al. has been carefully considered but is most respectfully traversed in view of the amendments to the claims and the following comments.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

> "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed.Cir. 1990).

The Official Action suggests that independent claims 1 and 5 lack novelty over US 5,276,094 (Kaszas). To reach this conclusion the Official Action seems to have ignored the feature (limitation) in these claims that the accelerator is a polysulphide compound derived from a substituted dithiocarbonic acid. As noted above, while a polysulphide compound derived from a substituted dithiocarbonic acid does perhaps indicate some history about the compound, it also imposes a product limitation as would be understood by one of ordinary skill in the art to which the invention pertains. The polysulphide compound is derived from a substituted dithiocarbonic acid and thus this limits the product in the sense that the claim does not encompass polysulphide compounds derived from an unrelated acid and is a claim limitation which cannot be ignored.

Moreover, it is urged on page 3 of the Official Action that, "The phrase 'for a valve for use in a pharmaceutical dispensing device' in claim 1, line 1 is not given any patentable weight since the applicant is introducing use limitations into the product claims (see MPEP 2173(q))." This statement is specifically traversed. MPEP 2173(a) is concerned with use claims which intend to claim a process without reciting steps and is not applicable to the present case. Claim 1 is not a method claim but a product claim, and the use described in claim 1 provides context for claim construction and to distinguish over the prior art. The appropriate MPEP section would appear to be MPEP

§2111.02 Effect of Preamble. Under the facts of the present case, full weigth is to be given to this limitation, which cannot be ignored.

More specifically, Kaszas relates to butyl elastomeric compositions for use in articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders (see column 1, lines 6 to 31). The curing system is discussed in column 8, lines 1 to 4, and comprises (i) metal oxide, (ii) sulphur, and (iii) at least one sulphur-based accelerator. Kaszas discloses the following accelerators: thiuram sulphides such as tetramethyl thiuram disulphide (TMTD), thiocarbamates such as zinc dimethyl thiocarbamates (ZDC) and the thiazyl and benzothiazyl compounds such as mercaptobenzothiazyl disulphide (MBTS) (see column 8, lines 10 to 18). The preferred accelerator is said to be tetramethyl thiuram disulphide (TMTD) (see also column 14, Table VI). The present application acknowledges the use of these known accelerators (see page 2 of the specification, lines 26-35).

As discussed on pages 3 and 4 of the of the present application, it has been found that tetramethyl thiuram disulphide (TMTD) (and also mercaptobenzothiazyl disulphide (MBTS)) is a precursor for the formation of nitrosamines, which are undesirable in seals for pharmaceutical dispensing devices. Thus, the use of these compounds in a curing system for use in the manufacture of a seal for a pharmaceutical dispenser device has this disadvantage (of course, there is no appreciation of this disadvantage in Kaszas since this document is not concerned with pharmaceutical dispenser devices). Furthermore, in most pharmaceutical applications, it is also necessary to extract or wash the cured elastomer in order to remove surface residues and by-products resulting from the cure reaction and moulding process. The aforementioned conventional cure/accelerator systems require relatively lengthy extraction times (typically 50 to 70 hours). Prolonged extraction times have been found to result in a deterioration in material properties.

The present invention solves these problems by the use of a cross-linking system in which:

sulphur or a sulphur-donating compound is used as a cross-linking agent (the cross-linking agent being free of peroxide curing agents), and

a polysulphide compound derived from a substituted dithiocarbonic acid or derivative thereof is used as an accelerator.

It is submitted that there is no teaching or suggestion of such a system in Kaszas. In particular, there is no mention in Kaszas of an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid such as xanthic acid. While Kaszas does mention dithiocarbamate compounds, these are salts of dithiocarbamic acid, i.e. NH_2CS_2H. Indeed, the present application acknowledges such accelerators on page 2, line 28 of the description. As will be appreciated, dithiocarbamic acid (NH_2CS_2H) is quite different from dithiocarbonic acid (carbonic acid is H_2CO_3) and Kaszas is silent regarding polysulphide compounds derived from a substituted dithiocarbonic acid, for example diisopropyl xanthogen polysulphide.

For the sake of completeness it is also pointed out that there is no mention in Kaszas of a seal for a valve for a pharmaceutical dispensing device (notwithstanding that the crosslinking system recited in the claims of the present application is neither taught nor suggested by Kaszas). Furthermore, Kaszas is not concerned with a valve for use in a pharmaceutical dispensing device (as claimed in claim 20), or a pharmaceutical dispensing device (as claimed in claims 21 and 22), or a dispensing apparatus for dispensing pressurised fluid (as claimed in claims 23 to 27).

Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claims 6-7 and 29 under 35 U.S.C. 103(a) as being unpatentable over Kaszas et al. in view of Simons et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to Kaszas et al. and the following comments.

Simons relates to a method of making gasketed closure elements for pressurized aerosol containers. This is an unrelated technical field to Kaszas, which is concerned with articles requiring low or reduced permeability to gases and improved tear strength, such as tire inner tubes, tire curing bladders and various air bladders. There would therefore be no motivation for one skilled in the art to combine these references. Simons is also not concerned with seals/valves for use in a pharmaceutical dispensing device. Accordingly, it is most respectfully requested that this rejection be withdrawn.

The rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Kaszas et al. in view of Stevenson et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the Kaszas reference and the following comments.

Stevenson relates an article such as an automobile component, for example a tire. An aircraft tire is specifically mentioned. Stevenson is plainly not concerned with seal and valves for use in a pharmaceutical dispensing device. There would therefore be no motivation for one skilled in the art to look to this reference when faced with the present invention.

The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Kaszas et al. in view of Blok et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the Kaszas reference and the following comments.

Blok relates to EPDM and EPR-based rubber compositions which are vulcanized with peroxide together with a specified combination of sulfur and acrylate co-agents. However, a requirement of claim 1 of the present application is that the cross-linking agent is free of peroxide curing agents. This means that Blok teaches away from the present invention and cannot render the claims obvious.

The rejection of claims 1, 8, 9 and 23-27 under 35 U.S.C. 103(a) as being unpatentable over Klokkers-Bethke et al. in view of Kaszas et al. has been carefully considered but is most respectfully traversed in view of the above comments as applied to the Kaszas reference and the following comments.

Klokkers-Bethke relates to a liquid nitroglycerin spray, desirably having a hydrophilic base, and a sealant material for a container having the spray composition therein and which sealant contacts the spray composition, the nitroglycerin absorption value of the sealant being less than 10 mg of nitroglycerin per one gram of sealant material. This is an unrelated technical field to Kaszas, which is concerned with articles requiring low or reduced permeability to gases and improved tear strength, such as tyre

inner tubes, tyre curing bladders and various air bladders. There would therefore be no motivation for one skilled in the art to combine these references. Certainly there would be no motivation to replace the seal in Klokkers-Bethke with the elastomer compositions described in Kaszas. There would be no expectation of success since the references pertain to unrelated technical fields. Even if the references were to be combined, there is no teaching in either document to use an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid. As submitted above this is a "product" limitation.

Neither Kaszas nor Klokkers-Bethke is concerned with reducing the formation of nitrosamines, which are undesirable in seals for a pharmaceutical dispensing apparatus such as a pharmaceutical metered does aerosol inhaler device. Neither Kaszas nor Klokkers-Bethke suggests the use of an accelerator which is a polysulphide compound derived from a substituted dithiocarbonic acid in combination with a sulphur cross-linking agent. Nor do Kaszas and Klokkers-Bethke contemplate the advantages of reduced extraction times associated with the use of such an accelerator. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all the claims now present in the application are most respectfully requested.

Respectfully submitted,
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